

Docket No.: A7542.0000/P001-H
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Ginette Serrero

Application No.: 10/607,974

Filed: June 30, 2003

Art Unit: 1635

For: 88KDA TUMORIGENIC GROWTH
FACTOR AND ANTAGONISTS

Examiner: T. Gibbs

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed within three months of the U.S. filing date (37 CFR 1.97(b)(1))

Those patents or publications which are marked with an asterisk (*) in the attached form PTO/SB/08 are not supplied because they were previously cited by or submitted to the Office in a prior application no. 09/813,156 filed March 21, 2001, which is a continuation of prior application 08/991,862 filed December 16, 1997, now U.S. Patent number 6,309,826, which is a Continuation-In-Part of prior application

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08/863,079, filed May 23, 1997, now abandoned and relied upon in this application for an earlier filing date under 35 U.S.C. 120.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1073, under Order No. A7542.0000/P001-H.

Dated: August 14, 2003

Respectfully submitted,

By 

James W. Brady, Jr.

Registration No.: 32,115

Jeremy A. Cubert

Registration No.: 40,399

DICKSTEIN SHAPIRO MORIN &

OSHINSKY LLP

2101 L Street NW

Washington, DC 20037-1526

(202) 785-9700

Attorneys for Applicant

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U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	*AA	5,416,192	05/16/1995	Shoyab et al.	
	*AB	6,309,826	10/30/2001	Serrero	
	*AC	6,511,986	01/28/2003	Zhang et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	*BA	WO 91 15510 A	10/17/1991	Squibb Bristol Myers Co.		

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NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²	
	*CA	<u>Effect of Testosterone on the Growth Properties and on Epidermal Growth Factor Receptor Expression in the Teratoma-derived Tumorigenic Cell Line 1246-3A</u> , Serrero, G. et al., Cancer Research 52, 1992, pps. 4242-4247.		
	*CB	<u>Molecular Biology of the Cell</u> , Alberts, B., et al., Garland Publishing, Inc., 1983.		
	*CC	<u>Growth Factors in Development, Transformation, and Tumorigenesis</u> , Cross, M. et al., Cell, Vol. 64, 1991, pps. 271-280.		
	*CD	<u>Autocrine Secretion and Malignant Transformation of Cells</u> , Sporn, M.B. et al., The New England Journal of Medicine, Vol. 303, 1980, pps. 878-880.		
	*CE	<u>Purification of an Autocrine Growth Factor Homologous with Mouse Epithelin Precursor from a Highly Tumorigenic Cell Line</u> , Zhou, J. et al., The Journal of Biological Chemistry, Vol. 268, No. 15, 1993, pps. 10863-10869.		
	*CF	<u>The Epithelin Precursor Encodes Two Proteins with Opposing Activities on Epithelial Cell Growth</u> , Plowman, G. et al., The Journal of Biological Chemistry, Vol. 267, No. 18, 1992, pps. 13073-13078.		
	*CG	<u>Granulins, a Novel Class of Peptide from Leukocytes</u> , Bateman, A. et al., Biochemical and Biophysical Research Communications, Vol. 173, No. 3, 1990, pps. 1161-1168.		
	*CH	<u>A Synthetic Fragment of Rat Transforming Growth Factor with Receptor Binding and Antigenic Properties</u> , Nestor, J. et al., Biochemical and Biophysical Research Communications, Vol. 129, No. 1, 1985, pps. 226-232.		
	*CI	<u>In Vitro Deletional Mutagenesis for Bacterial Production of the 20,000-Dalton Form of</u>		

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		<u>Human Pituitary Growth Hormone</u> , Adelman, J. et al., DNA, Vol. 2, No. 3, 1983, pps. 183-193.	
	*CJ	<u>An In Vitro Model to Study Adipose Differentiation in Serum-Free Medium</u> , Serrero, G. et al., Analytical Biochemistry 120, 1982, pps. 351-359.	
	*CK	<u>Study of a Teratoma-Derived Adipogenic Cell Line 1246 and Isolation of an Insulin-Independent Variant in Serum-Free Medium</u> , Serrero-Dave, G., Cancer Center, University of California, pps. 366-376.	
	*CL	<u>Tumorigenicity Associated with Loss of Differentiation and of Response to Insulin in the Adipogenic Cell Line 1246</u> , Serrero, G., In Vitro Cellular & Developmental Biology, Vol. 21, No. 9, 1985, pps. 537-540.	
	*CM	<u>Decreased Transforming Growth Factor-β Response and Binding in Insulin-independent Teratoma-Derived Cell Lines with Increased Tumorigenic Properties</u> , Serrero, G. et al., Journal of Cellular Physiology, 149, 1991, pps 503-511.	
	*CN	<u>Growth Inhibition of Human Breast Cancer Cells in Vitro with an Antibody against the Type I Somatomedin Receptor</u> , Arteaga, C. et al., Cancer Research 49, 1989, pps.6237-6241.	
	*CO	<u>The Biological Effects of a High Molecular Weight Form of IGF II in a Pluripotential Human Teratocarcinoma Cell Line</u> , Schofield, P. et al., Anticancer Research 14, 1994, pps. 533-538.	
	*CP	<u>Gene therapy of murine teratocarcinoma: Separate functions for insulin-like growth factors I and II in immunogenicity and differentiation</u> , Trojan, J. et al., Proc. Natl. Acad. Sci. USA, Vol. 91, 1994, pps. 6088-6092.	
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	*CR	<u>Treatment and Prevention of Rat Glioblastoma by Immunogenic C6 Cells Expressing Antisense Insulin-Like Growth Factor I RNA</u> , Trojan, J. et al., Science, Vol. 259, 1993, pps. 94-96.	
	*CS	<u>Continuous cultures of fused cells secreting antibody of predefined specificity</u> , Kohler, G. et al., Nature, Vol. 256, 1975, pps. 495-497.	
	*CT	<u>Production of Monoclonal Antibodies: Strategy and Tactics</u> , de St. Groth, S.F. et al., Journal of Immunology Methods, 35, 1980, pps. 1-21.	
	*CU	<u>Hybridoma Techniques</u> , Schreier, M. et al., Cold Spring Harbor Laboratory, 1980.	
	*CV	<u>Generation of antibody activity from immunoglobulin polypeptide chains produced in <i>Escherichia coli</i></u> , Cabilly, S. et al., Proc. Natl. Acad. Sci. USA, Vol. 81, 1984, pps. 3273-3277.	
	*CW	<u>Chimeric human antibody molecules: Mouse antigen-binding domains with human constant region domains</u> , Morrison, S. et al., Proc. Natl. Acad. Sci. USA, Vol. 81, 1984, pps. 6851-6855.	
	*CX	<u>Chimeric mouse-human IgG1 antibody that can mediate lysis of cancer cells</u> , Liu, A. et al., Proc. Natl. Acad. Sci. USA, Vol. 84, 1987, pps. 3439-3443.	
	*CY	<u><i>Escherichia coli</i> Secretion of an Active Chimeric Antibody Fragment</u> , Better, M. et al., Science, Vol. 240, 1988, pps. 1041-1043.	
	*CZ	<u>Reshaping human antibodies for therapy</u> , Riechmann, L. et al., Nature, Vol. 332, 1988, pps. 323-327.	

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*CAA	<u>Antibody Humanization Using Monovalent Phage Display</u> , Baca, M. et al., J. Biol. Chem., Vol. 272, No. 16, 1997, pps. 10678-10684.
*CBB	<u>A Combinatorial Library Strategy for the Rapid Humanization of Anticarcinoma BR96 Fab</u> , Rosok, M.J. et al., J. Biol. Chem., Vol. 271, No. 37, 1996, pps. 22611-22618.
*CCC	<u>Improved Radioimaging and Tumor Localization with Monoclonal F(ab')</u> , Wahl, R.L. et al., The Journal of Nuclear Medicine, Vol. 24, No. 4, 1983, pps. 316-325.
*CDD	<u>Clinical Use of a Monoclonal Antibody to Bombesin-like Peptide in Patients with Lung Cancer</u> , Mulshine, J.L., Annals New York Academy of Sciences, pps. 360-372.
*CEE	<u>Antisense RNA inhibits splicing of pre-mRNA <i>in vitro</i></u> , Munroe, S.H., The EMBO Journal, Vol. 7, No. 8, 1988, pps. 2523-2532.
*CFF	<u>Specific Synthesis of DNA <i>in Vitro</i> via a Polymerase-Catalyzed Chain Reaction</u> , Mulis, K.B. et al., Methods in Enzymology, Vol. 155, 1987, pps. 335-350.
*CGG	<u>Antisense approaches to cancer gene therapy</u> , Mercola, D. et al., Cancer Gene Therapy, Vol. 2, No. 1, 1995, pps 47-59.
*CHH	<u>Gene inhibition using antisense oligodeoxynucleotides</u> , Wagner, R. W., Nature, Vol. 372, 1994, pps. 333-335.
*CII	<u>Molecular Cloning: A Laboratory Manual</u> , Maniatis, T. et al., Cold Spring Harbor Laboratory, 1982.
*CJJ	<u>Design and Application of Antisense Oligonucleotides in Cell Culture, <i>in Vivo</i>, and as Therapeutic Agents</u> , Brysch, W. et al., Cellular and Molecular Neurobiology, Vol. 14, No. 5, 1994, pps. 557-568.
*CKK	<u>Rational Design of Sequence-specific Oncogene Inhibitors Based on Antisense and Antigene Oligonucleotides</u> , Helene, C., Eur. J. Cancer, Vol. 27, No. 11, 1991, pps. 1466-1471.
CLL	<u>Optimization of Antisense Oligodeoxynucleotide Structure for Targeting <i>ber-abl</i> mRNA</u> , Giles, R.V. et al., Blood, Vol. 86, No. 2, 1995, pps. 744-754.
*CMM	<u>Extending the chemistry that supports genetic information transfer <i>in vivo</i>: Phosphorothioate DNA, phosphorothioate RNA, 2'-O-methyl RNA, and methylphosphonate DNA</u> , Thaler, D.S. et al., Proc. Natl. Acad. Sci. USA, Vol. 93, 1996, pps. 1352-1356
*CNN	<u>Oligonucleotide N3'-P5' phosphoramidates as antisense agents</u> , Gryaznov, S. et al., Nucleic Acids Research, Vol. 24, No. 8, 1996, pps. 1508-1514.
*COO	<u>Cationic liposomes improve stability and intracellular delivery of antisense oligonucleotides into CaSki cells</u> , Lappalainen, K. et al., Biochimica et Biophysica Acta 1196, 1994, pps. 201-208.
*CPP	<u>Block of AIDS-Kaposi's Sarcoma (KS) Cell Growth, Angiogenesis, and Lesion Formation in Nude Mice by Antisense Oligonucleotide Targeting Basic Fibroblast Growth Factor</u> , Ensoli, B. et al., The Journal of Clinical Investigation, Inc., Vol. 94, 1994, pps. 1736-1746.
*CQQ	<u>Growth Inhibition of Malignant CD5+B (B-1) Cells by Antisense IL-10 Oligonucleotide</u> , Peng, B. et al., Leukemia Research, Vol. 19, No. 3, 1995, pps. 159-167.
*CRR	<u>Review: Optimizing inducer and culture conditions for expression of foreign proteins under the control of the lac promoter</u> , Donovan, R.S. et al., Journal of Industrial Microbiology, 16, 1996, pps. 145-154.

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*CSS	<u>Prokaryotic gene expression <i>in vitro</i>: Transcription-translation coupled systems</u> , Cenatiempo, Y., Biochimie, 68, 1986, pps. 505-515.
*CTT	<u>Bacterial Regulation: Global Regulatory Networks</u> , Gottesman, S., Ann. Rev. Genet., 18, 1984, pps. 415-441.
*CUU	<u>Regulation <i>In Vivo</i> of a Cloned Mammalian Gene: Cadmium Induces the Transcription of a Mouse Metallothionein Gene in SV40 Vectors</u> , Hamer, D.H. et al., Journal of Molecular and Applied Genetics, Vol. 1, No. 4, 1982, pps. 273-288.
*CVV	<u>Functional Relationships between Transcriptional Control Signals of the Thymidine Kinase Gene of Herpes Simplex Virus</u> , McKnight, S.L., Cell, Vol. 31, 1982, pps. 355-365.
*CWW	<u>Isolation of the yeast regulatory gene GAL4 and analysis of its dosage effects on the galactose/melibiose regulon</u> , Johnston, S.A. et al., Proc. Natl. Acad. Sci. USA, 79, 1982, pps. 6971-6975.
*CXX	<u><i>In vivo</i> sequence requirements of the SV40 early promoter region</u> , Benoist, C. et al., Nature, Vol. 290, 1981, pps. 304-310.
*CYY	<u>Cloning, Structure, and Expression of the Mitochondrial Cytochrome P-450 Sterol 26-Hydroxylase, a Bile Acid Biosynthetic Enzyme</u> , Andersson, S. et al., The Journal of Biological Chemistry, Vol. 264, No. 14, 1989, pps. 8222-8229.
*CZZ	<u>Insulin and Insulin-like Growth Factor Signaling Are Defective in the MDA MB-468 Human Breast Cancer Cell Line</u> , Sepp-Lorenzino, L. et al., Cell Growth & Differentiation, Vol. 5, 1994, pps. 1077-1083.
*CAAA	<u>Biochemical Analysis of the Epithelin Receptor</u> , Culouscou, J.M. et al., The Journal of Biological Chemistry, Vol. 268, No. 14, 1993, pps. 10458-10462.
*CBBB	<u>Targeted Toxins as Anticancer Agents</u> , Siegall, C.B., Cancer, Vol. 74, No. 3, 1994, pps. 1006-1012.
*CCCC	Zhang et al. <u>Proc. Natl. Acad. Sci. USA</u> . Vol. 95, pp. 14202-14207 (November 1998).
*CDDD	<u>Crooke, S.T. in Antisense Research and Application</u> (Stanley T. Crooke, Ed), Springer-Verlag, pp. 1-50, (July 1998).
*CEEE	Branch, A.D. <u>TIBS</u> . Vol. 23, pp. 45-50 (February 1998).
*CFFF	Gewirtz, A.M. et al. <u>Proc. Natl. Acad. Sci. USA</u> . Vol. 93, pp. 3161-3163 (April 1996).
*CGGG	Rojanasakul, Y. <u>Advanced Drug Delivery Reviews</u> , Vol. 18, pp. 115-131 (January 1996).
*CHHH	Anderson, W.F. <u>Nature</u> , Vol. 392, Suppl. pp. 25-30 (April 1998).
*CIII	Gura, T. <u>Science</u> , Vol. 278, pp. 1041-1042 (November 1997).
*CJJJ	Resnicoff, M. et al. <u>Cancer Res.</u> Vol. 54, pp. 2218-2222 (April 1994).
*CKKK	Zhang Haidi, "Overexpression of PC cell derived growth factor (PCDGF) contributes to the highly tumorigenic properties of producer cell line PC," DISS. ABSTR. INT., vol. 58, no. 11, 1998, page 5814-B XP001025915, abstract.
*CLLL	Vijay Bandhari and Andrew Bateman, "Structure and Chromosomal Location of the human granulin gene," Biochemical and Biophysical Research Communications, vol. 188, no. 1, 1992, pages 57-63, XP001018991, abstract, figure 2.
*CMMM	Bhandari et al., "The Complementary Deoxyribonucleic Acid Sequence, Tissue Distribution, and Cellular Localization of the Rat Granulin Precursor," Endocrinology, vol. 133, no. 6, 1993, pages 2682-2689, XP001021601.

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	*CNNN	Haidi Zhang and Ginette Serrero, "Inhibition of tumorigenicity of the teratoma PC cell line by transfection with antisense cDNA for PC cell-derived growth factor (PCDGF, epithelin/granulin precursor)," PNAS, vol. 95, November 1998 (1998-11), pages 14202-14207, XP002177206.	
	*COOO	European Search Report dated October 23, 2001	
	*CPPP	Sigmund, C.D., "Viewpoint: Are studies in genetically altered mice out of control? Arteriosclerosis Thrombosis and Vascular Biology, 2000, Vol. 20:1425-1429.	
	*CQQQ	Blackshear, P.E. Genetically engineered rodent models of mammary gland carcinogenesis: An overview. Toxicologic Pathology, 2001, Vol. 29:105-116.	
	*CRRR	Runqing Lu, et al. - "Inhibition of PC cell-derived growth factor (PCDGF, epithelin/granulin precursor) expression by antisense PCDGF cDNA transfection inhibits tumorigenicity of the human breast carcinoma cell line MDA-MB-468," PNAS, Vol. 97, No. 8, April 11, 2000, pgs. 3993-3998.	
	*CSSS	Bijay Bhandari et al. - "Isolation and sequence of the granulin precursor cDNA from human bone marrow reveals tandem cystein-rich granulin domains," Proc. Natl. Acad. Sci. USA, Vol. 89 March 1992, pgs. 1715-1719.	
	*CTTT	Zhiheng, He et al. - "Progranulin Gene Expression Regulates Epithelial Cell Growth and Promotes Tumor Growth <i>in Vivo</i> ¹ ," Cancer Research 59, July 1, 1999, pgs. 3222-3229.	
	*CUUU	International Search Report dated May 13, 2003.	

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